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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/431,469	11/01/99	ARMISTEAD	D VPI/95-09-DI
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HM22/0914

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EXAMINER

OGIHARA, N

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/14/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/431,469	Applicant(s) ARMISTEAD ET AL.	
	Examiner Nancy Ogiwara	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-18 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)                      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 20) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

- I. Claims 1-6, drawn to a crystal CnA protein, classified in class 530, subclass 350. If this group is elected, a species election is required for the organism from which the D1 protease is derived. If this group is elected, a species election is required for the protein association state.
- II. Claims 7-12, drawn to a machine readable storage medium storing crystallographic coordinate data, classified in class 345, subclass 521.
- III. Claim 13, drawn to a method of evaluating binding association of a ligand, classified in class 514, subclass 1.
- IV. Claims 14-15, drawn to a method of utilizing molecular replacement for structure determination, classified in class 702, subclass 27.
- V. Claims 16-18, drawn to a method of preparing CnA/CnB/FKBP12/FK506 crystal, , classified in class 540, subclass 350. If this group is elected, a species election is required for the digestion enzyme.

The inventions are distinct, each from the other because of the following reasons:

This application contains claims directed to the following patentably distinct species of the claimed invention.

**Group I, SPECIES REQUIREMENT**

For Group I, applicant must elect a type of protein association state selected from: (A) non (i.e. unliganded), or (B) a molecular complex.

Each of the types of association states are physically and functionally distinct protein conformations with different structural and biological properties.

**Group V SPECIES REQUIREMENT**

For Group V, Applicant must elect a species of digestion enzyme, selected from those listed in claim 17.

Each of the digestion enzymes are physically and functionally distinct chemical entities with different specificities, activities, and specificities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for Group I, claims 1-6 are generic for the association state. For Group V, claims 16 and 17 are generic for the digestion enzyme.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Groups I and V and (II-IV) are separate and distinct from each other as the critical feature of Groups I and V a protein crystal and the critical features of Groups II-IV are a computer readable medium and computational methods. The computer readable medium and computational methods are unrelated to the protein crystal of Groups I and V. As such the Inventions would require searching in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

Groups I and V are separate and distinct as the crystallized molecule of Group I encompasses forms of the CnA molecule not encompassed or required by the methods of preparation of Group V. For example, the crystal of group I can include unliganded forms, monomeric forms, complex forms with differing ligands, etc... As such the Inventions would require searching in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

Inventions II and (III and IV) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) a process for using the

Art Unit: 1631

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the computer readable medium of Group II can be used for word processing. As such the Inventions would require searching in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

Groups III and IV are separate and distinct as they are each drawn to differing methods with differing objectives, method steps, and outcomes. Group III results in the evaluation of binding of a ligand, whereas Group IV results in the structure of a molecule or complex. As such the Inventions would require searching in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

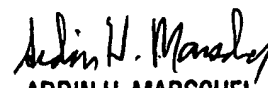
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Ogihara whose telephone number is (703) 308-9363. The examiner can be reached Monday-Friday from 8:30-6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Woodward can be reached at (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1631 by facsimile transmission. Papers should be faxed to Group 1631 via the PTO Fax Center located in Crystal Park I. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Nancy Ogihara  
September 12, 2000

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER